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New Phase 3 Data Show Stelara® Significantly Reduced Signs and Symptoms of Active Psoriatic Arthritis

Treatment with STELARA Also Resulted in Significant Improvements in Physical Function, Enthesitis and Dactylitis, and Plaque Psoriasis

Berlin, Germany, June 5, 2012 - Patients with active psoriatic arthritis receiving the interleukin (IL)-12/23 inhibitor STELARA® (ustekinumab) experienced significant improvements in signs and symptoms of the disease, according to new findings presented today from a Janssen Research & Development, LLC, (Janssen)-sponsored investigational study. Data from the 615-patient Phase 3 trial presented at the European League Against Rheumatism (EULAR) Annual Congress showed patients receiving STELARA 45 mg and 90 mg achieved the primary endpoint of the study, a significant reduction in arthritis signs and symptoms at week 24. Investigators reported STELARA-treated patients also achieved significant improvements in physical function, including dactylitis and enthesitis (two common manifestations of psoriatic arthritis which cause pain and swelling), as well as in plaque psoriasis. STELARA is currently being investigated in a Phase 3 program for the treatment of active psoriatic arthritis and is approved for the treatment of moderate to severe plaque psoriasis in 65 countries. *The EULAR press committee has selected the STELARA psoriatic arthritis study findings to be presented during the official EULAR press conference occurring Friday, June 8 from 9:00-9:45 CEST, which will take place in the Press Centre, Hall 6.3 at the congress.*

"Some 15 percent of patients living with psoriasis of the skin will develop psoriatic arthritis. This is a challenging disease that causes great distress for those afflicted, for which we currently have too few treatment options. These new findings showing the efficacy of STELARA in improving the joint symptoms of the disease are therefore important for rheumatologists and dermatologists," said Iain B. McInnes, Ph.D., Professor, Experimental Medicine and Rheumatology, Director of the Institute of Infection, Immunity, and Inflammation, University of Glasgow, Scotland, and study investigator. "We look forward to additional data from the Phase 3 psoriatic arthritis clinical development program to allow us to more fully assess the efficacy and safety of STELARA in the treatment of this complex inflammatory disease."

In the Phase 3 Multicenter, Randomized, Double-blind, Placebo-controlled trial of Ustekinumab, a Fully Human anti-IL-12/23p40 Monoclonal Antibody, Administered Subcutaneously, in Subjects with Active Psoriatic Arthritis (PSUMMIT I) study, patients with active psoriatic arthritis, despite treatment with disease-modifying antirheumatic drugs (DMARDs) and/or nonsteroidal anti-inflammatory drugs (NSAIDs), were randomized to receive subcutaneous STELARA 45 mg or 90 mg or placebo at weeks 0, 4 and then every 12 weeks. At week 24 of the trial, 42 percent and 50 percent of patients receiving STELARA 45 mg and 90 mg, respectively, achieved at least a 20 percent improvement in signs and symptoms according to American College of Rheumatology (ACR) criteria (ACR 20), the primary endpoint, compared with 23 percent of patients receiving placebo ($P < 0.001$). ACR responses were greater with STELARA than placebo regardless of methotrexate use. As measured by the ACR response criteria, significantly higher proportion of patients in the STELARA 45 mg and 90 mg groups also achieved approximately 50 percent improvement in signs and symptoms (ACR 50) and approximately 70 percent improvement in signs and symptoms (ACR 70) versus patients receiving placebo ($P < 0.001$ for all comparisons).

Study participants receiving STELARA achieved clinically relevant improvements in physical function, as measured by the Health Assessment Questionnaire Disability Index (HAQ-DI) and enthesitis (inflammation of the entheses, the sites where tendons or ligaments attach to bone) and dactylitis (inflammation of the finger or toe) scores. Changes from baseline in HAQ-DI at week 24 were significantly greater in the STELARA groups, and significantly greater proportions of STELARA-treated patients had a clinically meaningful change from baseline in HAQ-DI (defined as a change of at least 0.3) compared with patients in the placebo group. Among study participants affected with enthesitis (n=425) or dactylitis (n=286) at baseline, significantly greater improvements in symptoms were observed in patients receiving STELARA 45 mg or 90 mg than in patients receiving placebo based on median percent changes in the enthesitis score (-42.9 and -50.0 versus 0.0, respectively) and the dactylitis score (-75.0 and -70.8 vs. 0.0) [$P < 0.001$].

"These data provide important new insights into the efficacy of STELARA in the treatment of psoriatic arthritis across multiple disease measures," said Alice B. Gottlieb, M.D., Ph.D., Dermatologist-in-Chief and Chair of Dermatology, Tufts Medical Center, Harvey B. Ansell Professor of Dermatology, Tufts University School of Medicine, and study investigator. "For physicians who treat patients living with active psoriatic arthritis, the potential of STELARA, an IL-12/23 monoclonal antibody, for the treatment of this chronic, inflammatory disease is a promising development."

PSUMMIT I also assessed the efficacy of STELARA in the treatment of moderate to severe plaque psoriasis. Of 440 patients with at least three percent body surface involvement at the start of the study, 57 percent of patients receiving STELARA 45 mg and 62 percent of patients receiving STELARA 90 mg achieved at least a 75 percent improvement in psoriasis as measured by the Psoriasis Area Severity Index (PASI 75) score at week 24, compared with 11.0 percent of patients receiving placebo ($P <$

0.001).

Patients in the STELARA groups also reported statistically significant improvements in EULAR/Disease Activity Score (DAS) 28 C-reactive protein (CRP) responses. At week 24, 66 percent and 68 percent of patients receiving STELARA 45 mg and 90 mg, respectively, reported EULAR/DAS-CRP response compared with 34 percent of placebo patients ($P < 0.001$). The DAS 28 is a measure of disease activity in patients with arthritis that is calculated by assessing the number of tender and swollen joints (out of a total of 28), inflammation and the patient's assessment of global health. CRP is a type of protein produced in the liver and expressed during episodes of acute inflammation associated with arthritic conditions.

Treatment with STELARA was generally well-tolerated with similar proportions of patients experiencing at least one adverse event (AE) through week 16, the placebo-controlled period, among those receiving STELARA (42 percent) and placebo (42 percent). Serious AEs were reported in two percent of STELARA-treated patients and two percent of patients receiving placebo. No malignancies, cases of tuberculosis, serious infections, opportunistic infections, major adverse cardiovascular events (MACE) or deaths occurred through the placebo-controlled portion, week 16 of the study; one stroke occurred in the STELARA 45 mg group after the placebo-controlled period.

About PSUMMIT I

The PSUMMIT I trial is a Phase 3, multicenter, double-blind, placebo-controlled study including 615 adults with psoriatic arthritis designed to evaluate the efficacy and safety of STELARA in adults with psoriatic arthritis. The trial included patients diagnosed with active psoriatic arthritis who had at least five tender and five swollen joints and CRP levels of at least 0.3 mg/dL despite treatment with DMARDs and/or NSAIDs. Patients were naïve to treatment with anti-tumor necrosis factor (TNF)-alpha therapies and/or IL-12/23 inhibitors.

Patients were randomized to three groups: STELARA 45 mg or STELARA 90 mg at weeks 0, 4, and then every 12 weeks or placebo. At week 16, patients with less than a five percent improvement in tender and swollen joint counts were entered into early escape to receive STELARA 45 mg (patients receiving placebo) or STELARA 90 mg (patients receiving STELARA 45 mg). The primary endpoint was ACR 20 response at week 24. Secondary endpoints at week 24 included ACR 50 and ACR 70 response, DAS 28 using CRP (DAS28-CRP) response, PASI 75 in patients with at least three percent body surface area involvement at baseline, improvements in enthesitis and dactylitis scores and improvements in HAQ-DI scores.

About Psoriatic Arthritis

Psoriatic arthritis is a chronic immune-mediated inflammatory disease characterized by both joint inflammation and the skin lesions associated with psoriasis that affects up to 37 million people worldwide.[1] While estimates of the prevalence of psoriatic arthritis among people living psoriasis vary, up to 30 percent may develop inflammatory arthritis.[2] Though the exact cause of is unknown, genes, the immune system and environmental factors are all believed to play a role in the onset of the disease.[2]

About STELARA

STELARA, a human interleukin (IL)-12 and IL-23 antagonist, is approved for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. IL-12 and IL-23 are naturally occurring proteins that are believed to play a role in psoriasis.

STELARA is being investigated for the treatment of active psoriatic arthritis and is currently being evaluated in two Phase 3 randomized, double-blind, placebo-controlled multicenter trials.

Janssen Biotech, Inc. discovered STELARA and has exclusive marketing rights to the product in the United States. The Janssen pharmaceutical companies maintain exclusive worldwide marketing rights to STELARA, which is currently approved for the treatment of moderate to severe plaque psoriasis in 65 countries. For more information about STELARA, visit www.STELARAinfo.com.

Important Safety Information

STELARA® is a prescription medicine that affects your immune system. STELARA® can increase your chance of having serious side effects including:

Serious Infections

STELARA® may lower your ability to fight infections and may increase your risk of infections. While taking STELARA®, some people have serious infections, which may require hospitalization, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses.

- Your doctor should check you for TB before starting STELARA® and watch you closely for signs and symptoms of TB during treatment with STELARA®.
- If your doctor feels that you are at risk for TB, you may be treated for TB before and during treatment with STELARA®.

You should not start taking STELARA® if you have any kind of infection unless your doctor says it is okay.

Before starting STELARA®, tell your doctor if you think you have an infection or have symptoms of an infection such as:

- fever, sweats, or chills
- muscle aches
- cough
- shortness of breath
- blood in your phlegm
- weight loss
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- burning when you urinate or urinate more often than normal
- feel very tired
- are being treated for an infection
- get a lot of infections or have infections that keep coming back
- have TB, or have been in close contact with someone who has TB

After starting STELARA®, call your doctor right away if you have any symptoms of an infection (see above).

STELARA® can make you more likely to get infections or make an infection that you have worse. People who have a genetic problem where the body does not make any of the proteins interleukin 12 (IL-12) and interleukin 23 (IL-23) are at a higher risk for certain serious infections that can spread throughout the body and cause death. It is not known if people who take STELARA® will get any of these infections because of the effects of STELARA® on these proteins.

Cancer
STELARA® may decrease the activity of your immune system and increase your risk for certain types of cancer. Tell your doctor if you have ever had any type of cancer.

Reversible posterior leukoencephalopathy syndrome (RPLS)
RPLS is a rare condition that affects the brain and can cause death. The cause of RPLS is not known. If RPLS is found early and treated, most people recover. Tell your doctor right away if you have any new or worsening medical problems including: headache, seizures, confusion, and vision problems.

Serious Allergic Reactions
Serious allergic reactions can occur. Get medical help right away if you have any symptoms such as: feeling faint, swelling of your face, eyelids, tongue, or throat, trouble breathing, throat or chest tightness, or skin rash.

Before receiving STELARA®, tell your doctor if you:

- have any of the conditions or symptoms listed above for serious infections, cancer, or RPLS
- have recently received or are scheduled to receive an immunization (vaccine). People who take STELARA® should not receive live vaccines. Tell your doctor if anyone in your house needs a vaccine. The viruses used in some types of vaccines can spread to people with a weakened immune system, and can cause serious problems. **You should not receive the BCG vaccine during the one year before taking STELARA® or one year after you stop taking STELARA®**. Non-live vaccinations received while taking STELARA® may not fully protect you from disease.
- are receiving or have received allergy shots, especially for serious allergic reactions
- ever had an allergic reaction to STELARA®
- receive phototherapy for your psoriasis
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if STELARA® will harm your unborn baby. You and your doctor should decide if you will take STELARA®.
- are breast-feeding or plan to breast-feed. It is thought that STELARA® passes into your breast milk. You should not breast-feed while taking STELARA® without first talking to your doctor.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your doctor if you take:

- other medicines that affect your immune system
- certain medicines that can affect how your liver breaks down other medicines

Common side effects of STELARA® include: upper respiratory infections, headache, and tiredness

These are not all of the side effects with STELARA®. Tell your doctor about any side effect that bothers you or does not go away. Ask your doctor or pharmacist for more information.

Please read the Medication Guide for STELARA® and discuss any questions you have with your doctor.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

The U.S. full prescribing information for STELARA® can be accessed at the following link: http://www.stelarainfo.com/pdf/PrescribingInformation.pdf

About Janssen Research & Development, LLC

At Janssen Research & Development, LLC, we are united and energized by one mission-to discover and develop innovative medicines that ease patients' suffering, and solve the most important unmet medical needs of our time. As one of the Janssen Pharmaceutical Companies of Johnson & Johnson, our strategy is to identify the biggest unmet medical needs and match them with the best science, internal or external, to find solutions for patients worldwide. We leverage our world-class discovery and development expertise, and operational excellence, to bring innovative, effective treatments in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. For more information on Janssen R&D, visit http://www.janssenrnd.com/.

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[1]About Psoriasis: Statistics. National Psoriasis Foundation. Available at: http://www.psoriasis.org/learn_statistics. Accessed April 24, 2012.

[2]About Psoriatic Arthritis. National Psoriasis Foundation. Available at: http://psoriasis.org/psoriatic-arthritis. Accessed April 24, 2012.